may be released to the public without the affirmation of non-multinational status provided under FIFRA sec. 10(g), provided that the information does not contain or consist of any complete unpublished report submitted to EPA, or excerpts or restatements of any such report which reveal the full methodology and complete results of the study, test, or experiment, and all explanatory information necessary to understand the methodology or interpret the results.

§ 158.34 Flagging of studies for potential adverse effects.

(a) Any applicant who submits a study of a type listed in paragraph (b) of this section must submit with the study a statement in accordance with paragraph (c) of this section.

(b) The following table indicates the study types and the criteria to be applied to each. Column 1 lists the study types by name. Column 2 lists the associated Pesticide Assessment Guideline number. Column 3 lists the criteria applicable to each type of study. Column 4 lists the reporting code to be included in the statement specified in paragraph (c) of this section when any criterion is met or exceeded.

TABLE—FLAGGING CRITERIA

Study Type(s)	Guideline No.	Criteria: Treated animals show any of the following:	Criteria No.
Carcinogenicity or combined carcinogenicity/chronic feeding study	870.4200 870.4300	An incidence of neoplasms in males or females which increases with dose (positive trend p≤0.05); or	1
		A statistically significant (pairwise p≤0.05) increase of any type of neoplasm in any test group, males or females at any dose level, compared to concurrent control animals of the same sex; or	2
		An increase in any type of uncommon or rare neoplasms in any test group, males or females animals at any dose level, compared to concurrent controls of the same sex; or	3
		A decrease in the time to development of any type of neoplasms in any test group, males or females at any dose level, compared to concurrent controls of the same sex.	4
Prenatal developmental toxicity Reproduction and fertility Developmental neurotoxicity	870.3700 870.3800 870.6300	When compared to concurrent controls, treated offspring show a dose-related increase in malformations, pre- or post-natal deaths, or persistent functional or behavioral changes on a litter basis in the absence of significant maternal toxicity at the same dose level.	5
Neurotoxicity	870.6100 870.6200	When compared to concurrent controls, treated animals show a statistically or biologically significant increase in neuropathological lesions or persistent functional or behavioral changes.	6
Chronic feeding Carcinogenicity Reproduction and fertility Prenatal developmental toxicity Developmental neurotoxicity Acute or 90–day neurotoxicity	870.4100 870.4200 870.3800 870.3700 870.6300 870.6200	The no observed adverse effect level (NOAEL) from one of these studies is less than the NOAEL currently used by the Agency as the basis for either the acute or chronic reference dose.	7

(c) *Identification of studies.* For each study of a type identified in paragraph (b) of this section, the applicant shall include the appropriate one of the following two statements, together with the signature of the authorized representative of the company, and the date of signature:

(1) Study does not meet or exceed criteria.

I have applied the criteria of 40 CFR 158.34 for flagging studies for potential adverse effects to the results of the attached study. This study neither meets nor exceeds any of the applicable criteria.

(2) Study meets or exceeds criteria.

I have applied the criteria of 40 CFR 158.34 for flagging studies for potential adverse effects to the results of the attached study. This study meets or exceeds the criteria numbered [insert all applicable reporting codes].

§ 158.45 Waivers.

(a) The data requirements specified in this part as applicable to a category of products will not always be appropriate for every product in that category. Some products may have unusual physical, chemical, or biological properties or atypical use patterns which would make particular data requirements inappropriate, either because it would not be possible to generate the required data or because the data would not be useful in the Agency's evaluation of the risks or benefits of the product. The Agency will waive data requirements it finds are inappropriate, but will ensure that sufficient data are available to make the determinations required by the applicable statutory standards.

(b)(1) Applicants are encouraged to discuss a data waiver request with the Agency before developing and submitting supporting data, information, or other materials.

(2) All waiver requests must be submitted to the Agency in writing. The request must clearly identify the data requirement(s) for which a waiver is sought along with an explanation and supporting rationale why the applicant believes the data requirement should be waived. In addition, the applicant must describe any unsuccessful attempts to generate the required data, furnish any other information which the applicant(s) believe(s) would support the request, and when appropriate, suggest alternative means of obtaining data to address the concern which underlies the data requirement.

(c) The Agency will review each waiver request and subsequently inform the applicant in writing of its decision. If the decision could apply to more than the requested product, the Agency, in its discretion, may choose to send a notice to all registrants or publish a notice in the FEDERAL REGISTER announcing the decision. An Agency decision denying a written request to waive a data requirement is a final Agency action.

§ 158.60 Minor use data policies.

FIFRA sec. 2(ll) defines the term ''minor use''and FIFRA provides a number of statutory provisions concerning minor uses. In addition, EPA has established policies with respect to minor uses of pesticides, including, but not limited to, the following:

(a) A new data requirement pertinent to both an unregistered minor use and a registered major use will not be applied to a minor use applicant until it is applied to the major use registration.

(b) EPA will accept appropriate and adequate extrapolations and regional data to support establishment of individual minor use tolerances.

§ 158.70 Satisfying data requirements.

(a) *General policy*. The Agency will determine whether the data submitted or cited to fulfill the data requirements specified in this part are acceptable. This determination will be based on the design and conduct of the experiment from which the data were derived, and an evaluation of whether the data fulfill the purpose(s) of the data requirement. In evaluating experimental design, the Agency will consider whether generally accepted methods were used, sufficient numbers of measurements were made to achieve statistical reliability, and sufficient controls were built into all phases of the experiment. The Agency will evaluate the conduct of each experiment in terms of whether the study was conducted in conformance with the design, good laboratory practices were observed, and results were reproducible. The Agency will not reject data merely because they were derived from studies which, when initiated, were in accordance with an Agency-recommended protocol, even if the Agency subsequently recommends a different protocol, as long as the data fulfill the purposes of the requirements as described in this paragraph.

(1) The provisions in this part 158 should be read in conjunction with the provisions in §152.85 to claim eligibility for the formulators' exemption.

(2) [Reserved]